

U.S.S.N. 09/127,411  
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PRELIMINARY AMENDMENT WITH CPA

IN THE CLAIMS:

Please cancel claims 36, 155, 156, 157, 158, 159 and 162 without prejudice.

Please add claims 168-177 as follows:

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168. (New) A method for generating cells for immunotherapy, comprising:
- collecting leukocyte-containing material from a mammal, wherein the leukocyte-containing material from a mammal is obtained from an HIV<sup>+</sup> human; and
  - exposing the material to mitogenic monoclonal antibodies to induce *in vitro* cell proliferation sufficient for infusion into the mammal for use in an immunotherapy treatment, wherein:
    - the *in vitro* cell proliferation is produced without the use of exogenous IL-2;
    - CD4<sup>+</sup> cells in the material are purged of active virus by selection of CD4 antigen, and are polyclonally activated and again selected for CD4 antigen; and
    - in excess of 10<sup>10</sup> cells at a density of at least about 10<sup>8</sup> cells/ml are produced.
169. (New) The method of claim 168, wherein the CD4<sup>+</sup> cells are activated with immobilized anti-CD3 mab in the presence of gamma-interferon.
170. (New) The method of claim 37, wherein the conditions that promote Th1 cell differentiation to produce a population of cells that contains predominantly Th1 cells is selected from the group consisting of activation in the presence of gamma interferon, IL-12 and anti-IL-12 receptor antibodies.
171. (New) The method of claim 37, wherein after activation, the cells are grown in the presence of anti-CD28 monoclonal antibodies and gamma-interferon.
172. (New) The method of claim 168, wherein cells are activated by stimulation of the CD3 and CD28 cell surface antigens.

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173. (New) ~~The~~ method of claim 172, wherein activation is effected by contacting the cells with anti-CD3 and anti-CD28 antibodies.

174. (New) The method of claim 37, wherein cells are activated by stimulation of the CD3 and CD28 cell surface antigens.

175. (New) The method of claim 37, wherein cells are activated by contacting them with anti-CD3 and anti-CD28 antibodies.

176. (New) The method of claim 168, further comprising re-infusing the resulting cells into the HIV+ human.

177. (New) The method of claim 37, further comprising re-infusing the virally purged cells into the patient.

Please replace claims 37, 38, 39 and 154 with amended claims 37, 38, 39 and 154, as follows:

37. (Three Times Amended) A method of producing virally purged CD4+ cells, comprising:

- (a) collecting mononuclear cells from a patient infected with HIV;
- (b) contacting the cells with mitogenic antibodies to induce cell activation,

wherein, in the contacting step, the activation of the cells occurs under conditions that promote Th1 cell differentiation to produce a population of cells that contains predominantly Th1 cells;

- (c) selecting CD4+ cells that are HIV- after activation; and
- (d) inducing cell proliferation and expanding the selected cells to an excess of  $1 \times 10^{10}$  cells, wherein:

cell proliferation and expansion is performed in the absence of exogenous interleukin-2 (IL-2); and the cells are contained in a volume of a liter or less.

38. (Three Times Amended) The method of claim 37, further comprising: